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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,824	12/10/2001	Philippe Collas	50195/002002	7491

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CLARK & ELBING LLP
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EXAMINER
TON, THAIAN N

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 05/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/015,824	COLLAS ET AL.	
	Examiner	Art Unit	
	Thai-An N. Ton	1632	

-- The MAILING DATE of this communication app ars on the cover she t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-30 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 4, 14-16 and 18-23, drawn to methods of reprogramming a cell comprising incubating a chromatin mass or nucleus from a donor cell with a reprogramming media under conditions that allow the removal of a factor from the chromatin mass or nucleus, or the addition of a factor from the reprogramming media to the chromatin mass or nucleus, and inserting the nucleus or chromatin mass into a recipient cell or cytoplast, cells produced by the method, classified in class 435, subclass 377.

II. Claims 3, 4, 13 and 17-25, drawn to methods of reprogramming a cell by incubating a permeabilized cell with a reprogramming media under conditions that allow the removal of a factor from the nucleus or chromatin mass, or the addition of a factor from the reprogramming media to the nucleus or chromatin mass and cells produced by the method, classified in class 435, subclass 377.

III. Claim 5, drawn to a cell that expresses a T-cell receptor or IL-2 and one or more fibroblast-specific proteins, classified in class 435, subclass 325+.

IV. Claim 6, drawn to a cell that expresses a neurofilament protein and one or more fibroblast-specific proteins, classified in class 435, subclass 325+.

V. Claim 7, drawn to a cell that expresses that neurofilament protein NF200 and is immortalized, classified in class 435, subclass 325+.

VI. Claim 8, drawn to a cell that expresses Oct4 or alkaline phosphatase and one or more fibroblast-specific proteins, classified in class 435, subclass 325+.

VII. Claim 9, drawn to a cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies, classified in class 435, subclass 325+.

VIII. Claims 10, 11, 14-16, 18-23, 26 and 27, drawn to methods of treating or preventing a disease, disorder or condition in a mammal comprising incubating a nucleus or chromatin mass from a donor cell with a reprogramming media under conditions that allow the removal of a factor from the nucleus or chromatin mass or the addition of a factor from the reprogramming media, inserting the nucleus or chromatin mass into a recipient cell or cytoplast, and administering the resulting reprogrammed cell to a mammal, classified in class 424, subclass 93.1, 93.21.

IX. Claims 12, 13, 17-27, drawn to methods of treating or preventing a disease, disorder or condition in a mammal comprising incubating a permeabilized cell with a reprogramming media under conditions that allow removal of a factor from the nucleus or chromatin mass of the permeabilized cell or the addition of factor from the reprogramming media to the nucleus or chromatin mass, and administering the resulting reprogrammed cell to a mammal, classified in class 424, subclass 93.1, 93.21.

X. Claims 28-30, drawn to methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample, classified in class 435, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Invention I and any of Inventions II-VII, IX and X are mutually exclusive and independent. The methods of reprogramming a cell comprising incubating a chromatin mass or nucleus from a donor cell with a reprogramming media under conditions that allow the removal of a factor from the chromatin mass or nucleus, or the addition of a factor from the reprogramming media to the chromatin mass or nucleus, and inserting the nucleus or chromatin mass into a recipient cell or cytoplast of Invention I are not required for the implementation of the methods of reprogramming a cell by incubating a permeabilized cell with a reprogramming

media under conditions that allow the removal of a factor from the nucleus or chromatin mass, or the addition of a factor from the reprogramming media to the nucleus or chromatin mass of Invention II, the cell that expresses a T-cell receptor or IL-2 and one or more fibroblast-specific proteins of Invention III, the cell that expresses a neurofilament protein and one or more fibroblast-specific proteins of Invention IV, the cell that expresses that neurofilament protein NF200 and is immortalized of Invention V, the cell that expresses Oct4 or alkaline phosphatase and one or more fibroblast-specific proteins of Invention VI, the cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies of Invention VII, the methods of treatment of Invention IX, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions I and VIII are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Invention II and any of Inventions III-VIII and X are mutually exclusive and independent. The methods of reprogramming a cell by incubating a permeabilized

cell with a reprogramming media under conditions that allow the removal of a factor from the nucleus or chromatin mass, or the addition of a factor from the reprogramming media to the nucleus or chromatin mass of Invention II are not required for the cell that expresses a T-cell receptor or IL-2 and one or more fibroblast-specific proteins of Invention III, the cell that expresses a neurofilament protein and one or more fibroblast-specific proteins of Invention IV, the cell that expresses that neurofilament protein NF200 and is immortalized of Invention V, the cell that expresses Oct4 or alkaline phosphatase and one or more fibroblast-specific proteins of Invention VI, the cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies of Invention VII, the methods of treatment of Invention VIII, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions II and IX are related as process of making and process of using the product. The use as claimed cannot be practiced with a materially different product. Since the product is not allowable, restriction is proper between said method of making and method of using. The product claim will be examined along with the elected invention (MPEP § 806.05(i)).

Invention III and any of Inventions IV-X are mutually exclusive and independent. The cell that expresses a T-cell receptor or IL-2 and one or more

fibroblast-specific proteins of Invention III is not required for the cell that expresses a neurofilament protein and one or more fibroblast-specific proteins of Invention IV, the cell that expresses that neurofilament protein NF200 and is immortalized of Invention V, the cell that expresses Oct4 or alkaline phosphatase and one or more fibroblast-specific proteins of Invention VI, the cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies of Invention VII, the methods of treatment of Invention VIII, the methods of treatment of Invention IX, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa. Furthermore, each of the cells of Inventions III-VII are materially different cells that are not required for implementation of the other.

Invention IV and any of Inventions V-X are mutually exclusive and independent. The cell that expresses a neurofilament protein and one or more fibroblast-specific proteins of Invention IV is not required for the cell that expresses that neurofilament protein NF200 and is immortalized of Invention V, the cell that expresses Oct4 or alkaline phosphatase and one or more fibroblast-specific proteins of Invention VI, the cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies of Invention VII, the methods of treatment of Invention VIII, the methods of treatment of Invention IX, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa.

Furthermore, each of the cells of Inventions IV-VII are materially different cells that are not required for implementation of the other.

Invention V and any of Inventions VI-X are mutually exclusive and independent. The cell that expresses that neurofilament protein NF200 and is immortalized of Invention V is not required for the cell that expresses Oct4 or alkaline phosphatase and one or more fibroblast-specific proteins of Invention VI, the cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies of Invention VII, the methods of treatment of Invention VIII, the methods of treatment of Invention IX, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa. Furthermore, each of the cells of Inventions V-VII are materially different cells that are not required for implementation of the other.

Invention VI and any of Inventions VII-X are mutually exclusive and independent. The cell that expresses Oct4 or alkaline phosphatase and one or more fibroblast-specific proteins of Invention VI is not required for the cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies of Invention VII, the methods of treatment of Invention VIII, the methods of treatment of Invention IX, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa. Furthermore, each of the cells of

Inventions VI and VII are materially different cells that are not required for implementation of the other.

Invention VII and any of Inventions VIII-X are mutually exclusive and independent. The cell that expresses one or more fibroblast-specific proteins and grows in aggregates, forms colonies, or forms embryoid bodies of Invention VII is not required for the implementation of the methods of treatment of Invention VIII, the methods of treatment of Invention IX, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa.

Inventions VIII and either of Inventions IX or X are mutually exclusive and independent. The methods of treatment of Invention VIII are not required for the implementation of the methods of treatment of Invention IX, and the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Inventions IX and X are mutually exclusive and independent methods. The methods of treatment of Invention IX are not required for the implementation of the methods for measuring endogenous alkaline phosphatase protein in a cell, nucleus, chromatin mass, or *in vitro* sample of Invention X, and vice versa. Furthermore, each of the methods requires a separate and materially different protocol.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Deborah Crouch

DEBORAH CROUCH
PRIMARY EXAMINER
GROUP ~~1800~~ 1630

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thái-An N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to William Phillips, Patent Analyst, at (703) 305-3482. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 872-9306.

TNT

Thái-An N. Ton
Patent Examiner
Group 1632